CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
103948/0

CHEMISTRY REVIEW(S)
Review Memo

Ref: STN 103948

Prepared by: Kurt Borson, Ph.D., Staff Scientist, DMA
Through: Kathryn Stein, Ph.D., Director, DMA and Keith Webber Ph.D., Deputy Director, DMA
Sponsor: Millenium & Ilex partners (MPI)

Product: Campath

Date of submission: April 24, 2000
Date of review: May 2, 2001

Background
MPI has submitted a BLA for their anti-CD52 mAb, Campath, for use in CLL. The original BLA contained — months of drug product and drug substance stability data. In response to a CBER telephone request (May 2, 2001), MPI FAXed a 24-month update of stability data for drug product.

Conclusions
- Drug product was within specifications after 24 months of storage at 2-8°C.
Recommendation: approve 24 months as an initial expiry period for Campath drug product in conjunction with 6 months expiry for drug substance.
Telecon

Ref: STN 103948

Prepared by: Kurt Brorson, Ph.D., Staff Scientist, DMA

CBER:
Kurt Brorson, Ph.D., Staff Scientist, DMA
Kathryn Stein, Ph.D., Director, DMA
Keith Webber Ph.D., Deputy Director, DMA

Sponsor: Millenium & ILEX Partners (M&I)- Robert Petrusko

Product: Campath

Date: May 3, 2001, 11:00 AM

Background

M&I has submitted a BLA for their anti-CD52 mAb, Campath, for use in CLL. The original BLA contained proposed specifications for drug product and drug substance, including potency, % monomer (HPLC) and protein A.

Conclusions

- CBER requested a commitment from M&I to revise drug product specifications for potency, and % monomer (HPLC) and drug substance specifications for potency, % monomer (HPLC) and protein A after analysis of release data for worth of commercial lots, which ever came first. M&I agreed to submit a formal letter of commitment.

- CBER noted that an expiry period for storage could not be granted by the agency because M&I didn’t conduct a formal study examining the stability of drug product after storage of drug substance.